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Plaintiffs' Amended Requests for the Production of Documents

I. CORPORATE ORGANIZATION

1. **Produce organizational charts setting forth the corporate organization for each named defendant, from January 2010 to the present as follows:**
    a. **General corporate organizational charts for each defendant, including any affiliated entities involved in the manufacture, testing, distribution, or sale of valsartan;**
    b. **Medical affairs/clinical affairs department, or the equivalent;**
    c. **Quality assurance department, or the equivalent;**
    d. **Manufacturing department, including any departments involved in the manufacturing process for valsartan;**
    e. **Procurement Department;**
    f. **Sales department;**
    g. **Marketing department;**
    h. **Research and development department;**
    i. **Department(s) responsible for designing, funding, or supervising clinical trials (including all Phase I, II, III, and IV);**
    j. **Regulatory department;**
    k. **Department responsible for epidemiology and/or statistical analysis;**
    l. **Department responsible for providing professional education to physicians;**
    m. **Department(s) responsible for establishing or maintaining relationships involving valsartan, with any other defendant named in this MDL.**

Plaintiffs' Basis for Request: Organizational information is basic, non-privileged, and relevant. That certain Defendants (e.g., ZHP) have (finally) produced a few organizational charts for certain departments does not mean any Defendant should be relieved from producing organizational charts subsequently identified in custodial and non-custodial files.

2. **Produce organizational charts or similar documents setting forth:**
    a. **All corporate officers;**
    b. **All members of the Board of Directors;**
    c. **All persons or entities which own or owned 5% or more of defendant's common stock.**

Plaintiffs' Basis for Request: *See* Request No. 1

3. **To the extent you conduct business relating to the manufacture, distribution, or marketing of valsartan with any other defendant in the above-captioned MDL, produce documents, including contracts, invoices, payment records, and communications, demonstrating the nature, extent, and length of this business relationship.**

Plaintiffs' Basis for Request: *See* Request No. 1

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II. RELEVANT CUSTODIANS

4. **Produce documents identifying the corporate employees or retained third parties responsible for or involved in the (1) manufacture, (2) testing, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments, (6) regulatory activities, (7) communications with regulatory agencies, (8) distribution, (9) production, (10) packaging, (11) sale, (12) marketing, and (13) communications with private individuals or entities regarding safety, bioequivalence, purity, contamination, and pricing, with regard to valsartan.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request

III. POLICIES AND PROCEDURES

5. **Produce all final versions of policies, procedures, standard operating procedures, or protocols for or relevant to the (1) manufacture, (2) testing, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments, (6) regulatory activities, (7) communications with regulatory agencies, (8) production, (9) distribution, (10) packaging, (11) sale, (12) marketing, and (13) communications with private individuals or entities, regarding safety, bioequivalence, purity, contamination, and pricing, with regard to valsartan, and/or the ingredients thereof. In addition, provide all indexes or lists of the requested documents.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

IV. AGREEMENTS

6. **Produce all agreements, contracts, or licenses that the answering defendant is a party to, with regard to (1) the manufacturing process, (2) testing for bioequivalence, purity, or contamination, (3) quality assurance, (4) risk assessment, (5) medical and clinical assessments of bioequivalence, purity, or contamination, (6) regulatory activities, (7) communications with regulatory agencies, (8) production, (9) distribution, (10) packaging, (11) sale, (12) marketing, (13) communications with private individuals or entities, regarding safety, bioequivalence, purity, contamination, and pricing, and (14) procurement of components or ingredients, with regard to valsartan and/or its ingredients.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

7. **Produce all agreements, memoranda, and payment or expense records, with regard to any attempt by defendant to retain, engage or otherwise provide financial support or item of value to any person with regard to proposed or actual scientific or medical study of valsartan.**

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Plaintiffs' Basis for this Request: The Parties do not dispute this request.

8. **Produce all agreements to engage any third party to represent your interests before the FDA or any regulatory authority, with regard to valsartan.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

9. **Produce all agreements with regard to the retention of persons in any medical or scientific discipline to study, assess or analyze the safety, purity, or contamination of valsartan for or on behalf of any defendant.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

V. INTRA-DEFENDANT COMMUNICATIONS

10. **All communications between or among any of the defendants with regard to. (1) the manufacturing process, (2) testing capable of indicating purity, bioequivalence, or contamination, (3) quality assurance related to purity, bioequivalence, or contamination, (4) risk assessment with regard to contamination or the use of solvents, (5) medical and clinical assessments of risks related to impurity or contamination, (6) communications with regulatory agencies regarding bioequivalence, purity, or contamination, (7) terms or conditions of distribution, (8) sale numbers, (9) pricing, and (10) procurement or use of solvents, with regard to valsartan.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

VI. ANDA AND DMF

11. **To the extent any ANDA file for valsartan was not produced in whole or in part during Core Discovery, produce the entire file, whether or not ultimately approved [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].**

Plaintiffs' Basis for this Request: Defendants dispute this request insofar as Plaintiffs request unapproved, tentatively approved, or withdrawn ANDAs. Plaintiffs are entitled to review unapproved, tentatively approved and withdrawn ANDA applications for all of Defendants valsartan products to be able to assess the processes used for these products, and any communications the FDA had with the Defendants regarding these products. ANDA files are centrally kept and do not pose a great burden for Defendants.

12. **Produce all correspondence with the FDA concerning any ANDA for valsartan, whether or not ultimately approved, including prior to the relevant time period set by the Court [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].**

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Plaintiffs' Basis for this Request: Defendants dispute this request insofar as it requests unapproved tentatively approved or withdrawn ANDAs. Plaintiffs are entitled to review unapproved, tentatively approved and withdrawn ANDA applications for all of Defendants valsartan products to be able to assess the processes used for these products, and any communications the FDA had with the Defendants regarding these products. ANDA files are centrally kept and do not pose a great burden for Defendants.

13. **Produce all documents containing the list of ingredients in valsartan, which were provided to any regulatory authority, beginning from the date you first began development of the process for manufacturing the API for valsartan [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].**

Plaintiffs' Basis for this Request: Defendants dispute this request insofar as it requests unapproved tentatively approved or withdrawn ANDAs. Plaintiffs are entitled to review unapproved, tentatively approved and withdrawn ANDA applications for all of Defendants valsartan products to be able to assess the processes used for these products, and any communications the FDA had with the Defendants regarding these products. ANDA files are centrally kept and do not pose a great burden for Defendants.

14. **Produce all documents relating to New Drug Applications filed by you with regard to valsartan, beginning from the date you first began development of the process for manufacturing the API for valsartan [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].**

Plaintiffs' Basis for this Request: Defendants dispute this request insofar as Plaintiffs request unapproved, tentatively approved, or withdrawn ANDAs. Plaintiffs are entitled to review unapproved, tentatively approved and withdrawn ANDA applications for all of Defendants valsartan products to be able to assess the processes used for these products, and any communications the FDA had with the Defendants regarding these products. ANDA files are centrally kept and do not pose a great burden for Defendants.

15. **Produce all complete drug master files for valsartan, to the extent not produced to date. [Plaintiffs seek an exception to the Court's general relevant time period ruling on this request].**

Plaintiffs' Basis for this Request: Defendants have represented they have produced all DMF files for Valsartan API, so the Parties do not dispute this request.

VII. LITIGATION AND DOCUMENT PRESERVATION

16. **Produce all document retention or destruction policies.**

Plaintiffs' Basis for this Request: Defendants' document retention policies are needed to assist Plaintiffs in understanding Defendants' overall compliance with current Good Manufacturing practices ("cGMPs"), which require Defendants to maintain a certain set of documents pursuant

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to federal regulations. Defendants' document retention policies are also relevant for the issue of spoliation.

17. [WITHDRAWN]
18. [WITHDRAWN]

VIII. MANUFACTURING

19. **Produce all documents with regard to the manufacturing process for the active pharmaceutical ingredient in valsartan, including any modifications thereto.**

Plaintiffs' Basis for this Request: While Defendants have agreed to produce a set of documentation regarding manufacturing, Defendants disagree with Plaintiffs position insofar as Plaintiffs are seeking a limited and discrete set of documents which pre-date the discovery time periods set by the Court. However, Plaintiffs believe this limited set of documents (reports and analyses created to document changes in the manufacturing process) prior to 2010 or 2011 are necessary to understand the timeline of the process, and to inform upon later changes made to the process.

20. **Produce all documents with regard to the machines, materials, and substances (including but not limited to new or recycled solvents, tainted or contaminated solvents) utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan, including specifications, manuals, material safety data sheets, machine settings and calibrations, and any modifications thereto.**

Plaintiffs' Basis for this Request: While Defendants have agreed to produce a set of documentation regarding manufacturing, Defendants disagree with Plaintiffs position insofar as Plaintiffs are seeking a limited and discrete set of documents which pre-date the discovery time periods set by the Court. However, Plaintiffs believe this limited set of documents (reports and analyses created to document changes in the manufacturing process) prior to 2010 or 2011 are necessary to understand the timeline of the process, and to inform upon later changes made to the process.

21. **Produce all documents (including photographs or video) with regard to any testing or inspections of the machines, materials, and substances utilized in the manufacturing process for the active pharmaceutical ingredient in valsartan.**

Plaintiffs' Basis for this Request: While Defendants have agreed to produce a set of documentation regarding manufacturing, Defendants disagree with Plaintiffs position insofar as Plaintiffs are seeking a limited and discrete set of documents which pre-date the discovery time periods set by the Court. However, Plaintiffs believe this limited set of documents (reports and analyses created to document changes in the manufacturing process) prior to 2010 or 2011 are necessary to understand the timeline of the process, and to inform upon later changes made to the process.

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22. **Produce all documents setting forth the manufacturing/fabrication/production process for the finished drug formulation of valsartan sold by you or any of your affiliated entities, including any quality assurance and testing, and any modifications thereto.**

Plaintiffs' Basis for this Request: While Defendants have agreed to produce a set of documentation regarding manufacturing, Defendants disagree with Plaintiffs position insofar as Plaintiffs are seeking a limited and discrete set of documents which pre-date the discovery time periods set by the Court. However, Plaintiffs believe this limited set of documents (reports and analyses created to document changes in the manufacturing process) prior to 2010 or 2011 are necessary to understand the timeline of the process, and to inform upon later changes made to the process.

23. **Produce the patent(s) for any patented device, machine, or technology utilized in the testing of valsartan for unknown peaks, impurities (elemental or otherwise), and residual solvents in either the valsartan API or the finished dose versions of your VCDs.**

Plaintiffs' Basis for this Request: The Parties have no current dispute because Defendants have agreed to produce a set of documentation regarding manufacturing.

24. **Produce all patents filed by you or employees and/or agents associated with you, with any foreign regulatory body regarding the manufacturing process for valsartan.**

Plaintiffs' Basis for this Request: The Parties have no current dispute because Defendants have agreed to produce a set of documentation regarding manufacturing.

25. **Produce documentation demonstrating the name, address, and role of any third party which supplied you with valsartan or any ingredient, material, or component used in the manufacture of valsartan, and any evaluation or testing thereof.**

Plaintiffs' Basis for this Request: The Parties have no current dispute because Defendants have agreed to produce a set of documentation regarding manufacturing.

26. **Produce all certificates of analysis or similar documents concerning analysis of the purity or contents of valsartan, and documents and communications concerning the same.**

Plaintiffs' Basis for this Request: The Parties have no current dispute because Defendants have agreed to produce a set of documentation regarding manufacturing.

27. **Produce documentation identifying (1) each lot, batch, or other production quantity of valsartan manufactured, purchased, or sold by defendant (including discarded or recalled lots or batches), (2) the dates of manufacture for each, (3) the solvent(s) (including residual or reused solvents) utilized in the manufacture of each, and (4)**

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any information you obtained with regard to potential risks of the use of any solvent utilized, including residual or reused solvents.

Plaintiffs' Basis for this Request: The Parties have no current dispute because Defendants have agreed to produce a set of documentation regarding manufacturing.

28. **Produce documentation of all scientific journal articles submitted to any academic or scientific publication, written or drafted in whole, or in part, by your employees or scientists or third parties who received funding or other forms of compensation from you, regarding the manufacturing of valsartan, including the final version, any drafts, edits, and peer reviewed feedback.**

Plaintiffs' Basis for this Request: The Parties have no current dispute because Defendants have agreed to produce a set of documentation regarding manufacturing.

29. **All communications and documents exchanged between you and any third party, regarding the manufacturing process associated with the creation of valsartan, including but not limited to the use of solvents, the tetrazole ring formation process, testing, and contamination issues.**

Plaintiffs' Basis for this Request: The Parties have no current dispute because Defendants have agreed to produce a set of documentation regarding manufacturing.

IX. BIOEQUIVALENCE

30. **All documentation of the bioequivalence of any valsartan sold or manufactured (in whole or in part) by you to the Reference Listed Drug ("RLD"), including but not limited to, testing, communications with the FDA, communications with customers, suppliers, or other third parties, and certifications of bioequivalence.**

Plaintiffs' Basis for this Request: The Court has already found that bioequivalence data is relevant and Plaintiffs require these documents to understand whether Defendants complied with their duties of sameness as required by federal regulation as ANDA holders.

31. **All marketing materials referencing the bioequivalence of valsartan manufactured, distributed, or marketed by you.**

Plaintiffs' Basis for this Request: The Court has already found that bioequivalence data is relevant and Plaintiffs require these documents to understand whether Defendants complied with their duties of sameness as required by federal regulation as ANDA holders.

32. **All documents and communications regarding the identification by any person or entity of any valsartan manufactured, utilized, or sold by or to you as not being bioequivalent to the RLD.**

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Plaintiffs' Basis for this Request: The Court has already found that bioequivalence data is relevant and Plaintiffs require these documents to understand whether Defendants complied with their duties of sameness as required by federal regulation as ANDA holders.

33. **All documents and communications relevant to valsartan entries in the FDA's "Orange Book."**

Plaintiffs' Basis for this Request: The Court has already found that bioequivalence data is relevant and Plaintiffs require these documents to understand whether Defendants complied with their duties of sameness as required by federal regulation as ANDA holders.

34. **Documentation of any patent litigation between you and either the Brand Manufacturer of the RLD regarding valsartan, or other generic companies which had filed an ANDA application for a valsartan product.**

Plaintiffs' Basis for this Request: The Court has already found that bioequivalence data is relevant and Plaintiffs require these documents to understand whether Defendants complied with their duties of sameness as required by federal regulation as ANDA holders.

X. TESTING

35. **Produce all documents setting forth or addressing the results of any testing (including chromatography) of valsartan that had the potential to directly or indirectly identify impurities or contamination.**

Plaintiffs' Basis for this Request: Plaintiffs cannot limit these requests to any specific tests without first receiving full lists of all testing conducted on valsartan API and finished dose from each manufacturer defendant, as well as the limited production of internal documents consisting of deviation reports and investigations provided to the FDA in the course of inspections.

36. **Produce all documentation with regard to the first test that indicated impurity or contamination of valsartan that was potentially due to a nitrosamine, whether or not identified as nitrosamine contamination at the time.**

Plaintiffs' Basis for this Request: Plaintiffs cannot limit these requests to any specific tests without first receiving full lists of all testing conducted on valsartan API and finished dose from each manufacturer defendant, as well as the limited production of internal documents consisting of deviation reports and investigations provided to the FDA in the course of inspections.

37. **Produce all documentation with regard to each notification to defendant of impurity or contamination of valsartan that was, or potentially was, due to a nitrosamine, whether or not identified as nitrosamine contamination at the time. In connection with this request, separately identify the first such notification.**

Plaintiffs' Basis for this Request: Plaintiffs cannot limit these requests to any specific tests without first receiving full lists of all testing conducted on valsartan API and finished dose from

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each manufacturer defendant, as well as the limited production of internal documents consisting of deviation reports and investigations provided to the FDA in the course of inspections.

38. [WITHDRAWN]

39. **Produce all documents with regard to evaluation by an employee of defendant or a third party, with regard to the health risks of valsartan contamination as limited by the Court's Order.**

Plaintiffs' Basis for this Request: Plaintiffs cannot limit these requests to any specific tests without first receiving full lists of all testing conducted on valsartan API and finished dose from each manufacturer defendant, as well as the limited production of internal documents consisting of deviation reports and investigations provided to the FDA in the course of inspections.

40. **Produce documentation of all studies of the ingredients, impurities, and actual or potential contamination, of valsartan conducted by any third parties, including, but not limited to, those conducted by Contract Research Organizations (CRO), educational institutions, publicly or independently funded groups, competitors, trade groups or associations, regulatory entities, irrespective of whether such studies were conducted at the direction of Defendant.**

Plaintiffs' Basis for this Request: Plaintiffs cannot limit these requests to any specific tests without first receiving full lists of all testing conducted on valsartan API and finished dose from each manufacturer defendant, as well as the limited production of internal documents consisting of deviation reports and investigations provided to the FDA in the course of inspections.

41. **Produce documentation of any report or analysis made known to Defendant with regard to the relationship between the use of contaminated valsartan and potential or confirmed injuries; and the review of same by any employee or consultant of Defendant.**

Plaintiffs' Basis for this Request: Plaintiffs are aware that Defendants have contracted with third-party toxicologists and epidemiologists. They are entitled to discovery documents about these studies, including which data these experts reviewed, and what documents they were provided.

42. **Provide documentation of the results of any clinical or animal study regarding valsartan conducted with potentially contaminated valsartan during the relevant time period, whether or not sponsored by, financed by, undertaken by, or suggested by Defendant, and any internal analysis thereof.**

Plaintiffs' Basis for this Request: Plaintiffs are aware that Defendants have contracted with third-party toxicologists and epidemiologists. They are entitled to discovery documents about these studies, including which data these experts reviewed, and what documents they were provided.

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43. **Produce documentation of any epidemiology studies or analyses known to defendant regarding valsartan, including but not limited to, any provided to or received from any regulatory authority, together with the underlying data including for example SAS data sets, and any internal analysis thereof.**

Plaintiffs' Basis for this Request: Plaintiffs are aware that Defendants have contracted with third-party toxicologists and epidemiologists. They are entitled to discovery documents about these studies, including which data these experts reviewed, and what documents they were provided.

44. **Produce complete documentation of (a) all testing relevant to determination of purity, bioequivalence, or contamination, prior to any recall, of valsartan you manufactured or sourced, (b) all testing relevant to determination of purity, bioequivalence, or contamination,, after any recall, of valsartan you manufactured or sourced, (c) the results of the foregoing testing; (d) any such testing that was considered but not performed before or after any recall, including the reason(s) why such testing was not performed, and (e) to the extent any lot, batch, or other production quantity was not tested for impurities, bioequivalence or contamination, complete documentation with regard to the reason(s) why no such testing was performed.**

Plaintiffs' Basis for this Request: Defendants themselves have made this request necessary, as they have informed Plaintiffs (and the Court) that they reserve their rights to solely provide bioequivalence stability data provided to the FDA as part of the ANDA application. Furthermore, Plaintiffs cannot limit these requests to any specific tests without first receiving full lists of all testing conducted on valsartan API and finished dose from each manufacturer defendant, as well as the limited production of internal documents consisting of deviation reports and investigations provided to the FDA in the course of inspections.

XI. NITROSAMINES AND CONTAMINATION

45. **Produce complete documentation identifying each lot, batch, or other production quantity of valsartan, (a) confirmed to be contaminated and the quantification of the contamination; (b) assumed to have been contaminated and the quantification of the contamination; (c) confirmed not to be contaminated; (d) assumed not to be contaminated, and (e) confirmed or assumed to be contaminated.**

Plaintiffs' Basis for this Request: Plaintiffs' requests related to nitrosamines and contaminations drive right to the heart of the entire litigation.

46. **Produce complete documentation of any testing for any nitrosamine compound, including but not limited to NDMA, NDEA, NMBA, and any other nitrosamine or carcinogenic contaminant in valsartan, or any other API or finished drug manufactured, formulated, distributed, or sold by the answering defendant, as limited by the Court's Order.**

Plaintiffs' Basis for this Request: Plaintiffs' requests related to nitrosamines and contaminations drive right to the heart of the entire litigation.

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47. **Produce complete documentation of any testing or research conducted by you or a third party on your behalf to determine the existence or quantification of contamination in any valsartan API or finished drug formulation.**

Plaintiffs' Basis for this Request: Plaintiffs' requests related to nitrosamines and contaminations drive right to the heart of the entire litigation.

48. **Produce complete documentation with regard to the analysis of health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance, conducted by you or any third party on your behalf.**

Plaintiffs' Basis for this Request: Plaintiffs' requests related to nitrosamines and contaminations drive right to the heart of the entire litigation.

49. **Produce all studies, data, or other scientific or medical information reviewed or considered by any employee or third party on your behalf with regard to the health risks due to contamination of valsartan with any nitrosamine or other carcinogenic substance.**

Plaintiffs' Basis for this Request: Plaintiffs' requests related to nitrosamines and contaminations drive right to the heart of the entire litigation.

50. **Produce all formal or informal reports or complaints by or to Defendant or any other person or entity to your knowledge, with regard to valsartan contamination.**

Plaintiffs' Basis for this Request: Plaintiffs' requests related to nitrosamines and contaminations drive right to the heart of the entire litigation.

51. **Produce all documents known to you, embodying any analysis or opinion by any person or entity, regarding the potential health risks of nitrosamine contamination of valsartan.**

Plaintiffs' Basis for this Request: Plaintiffs' requests related to nitrosamines and contaminations drive right to the heart of the entire litigation.

XII. REGULATORY CORRESPONDENCE AND DOCUMENTS

52. **Produce all regulatory documentation and communications with regard to contamination or recalls of valsartan, as limited by the Court's Order.**

Plaintiffs' Basis for this Request: The Parties dispute this request for two discrete reasons. First, Plaintiffs believe they are entitled to any regulatory communication related to the recalls or contamination of Valsartan that pertain to unapproved, tentatively approved or withdrawn ANDA applications. Plaintiffs are entitled to see what Defendants were saying about these products, and how these communications were the same, or different, then communications for approved

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products. Second, Plaintiffs request confirmation that Defendants will produce communications with foreign regulatory bodies to the extent they discuss potential nitrosamine contaminations. Defendants have defined potential nitrosamine contaminations as "unknown peaks which appear on tests capable of detecting nitrosamine contaminations." Plaintiffs believe this definition is circular, and would exclude almost all documentation, as by Defendants' own telling, the only test capable of detecting nitrosamines was developed *after* the recall.

53. **Produce all regulatory documentation and communications with regard to the use of solvents, tetrazole ring formation, and potential impurities or contamination in connection with the manufacturing process for valsartan.**

Plaintiffs' Basis for this Request: The Parties dispute this request for two discrete reasons. First, Plaintiffs believe they are entitled to any regulatory communication related to the recalls or contamination of Valsartan that pertain to unapproved, tentatively approved or withdrawn ANDA applications. Plaintiffs are entitled to see what Defendants were saying about these products, and how these communications were the same, or different, then communications for approved products. Second, Plaintiffs request confirmation that Defendants will produce communications with foreign regulatory bodies to the extent they discuss potential nitrosamine contaminations. Defendants have defined potential nitrosamine contaminations as "unknown peaks which appear on tests capable of detecting nitrosamine contaminations." Plaintiffs believe this definition is circular, and would exclude almost all documentation, as by Defendants' own telling, the only test capable of detecting nitrosamines was developed *after* the recall.

54. **Produce transcripts, notes, memoranda, or other documentation of any hearings or other proceedings or meetings which took place at or with any regulatory agency relating to the actual and/or potential contamination or recall of valsartan.**

Plaintiffs' Basis for this Request: The Parties dispute this request for two discrete reasons. First, Plaintiffs believe they are entitled to any regulatory communication related to the recalls or contamination of Valsartan that pertain to unapproved, tentatively approved or withdrawn ANDA applications. Plaintiffs are entitled to see what Defendants were saying about these products, and how these communications were the same, or different, then communications for approved products. Second, Plaintiffs request confirmation that Defendants will produce communications with foreign regulatory bodies to the extent they discuss potential nitrosamine contaminations. Defendants have defined potential nitrosamine contaminations as "unknown peaks which appear on tests capable of detecting nitrosamine contaminations." Plaintiffs believe this definition is circular, and would exclude almost all documentation, as by Defendants' own telling, the only test capable of detecting nitrosamines was developed *after* the recall.

55. **Produce all documents with regard to any FDA Advisory Panel meetings regarding valsartan contamination.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

56. **Produce all Establishment Inspection Reports (including foreign regulatory equivalents of Establishment Inspection Reports) and related documentation**

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(including photographs or video) concerning your facilities or the facilities of any other defendant used in the manufacture, fabrication, packaging, distribution, or sale of valsartan.

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

57. **Produce all documents relating, referring to or embodying all inspection reports (including 483s, detention reports, and warning letters, or consent decrees, including foreign regulatory equivalents) which pertain in any way to valsartan contamination or any facility in which contaminated valsartan was manufactured.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

58. **Produce complete documentation regarding any CAPAs (Corrective and Preventative Actions) relating to the manufacture of valsartan, including documentation showing what caused the CAPA to be opened and/or closed.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

59. **Produce all documentation, and related communications, of any complaints or third party communications to or from any regulatory agency with regard to actual or potential valsartan contamination.**

Plaintiffs' Basis for this Request: Plaintiffs request confirmation that Defendants will produce communications with foreign regulatory bodies to the extent they discuss potential nitrosamine contaminations. Defendants have defined potential nitrosamine contaminations as "unknown peaks which appear on tests capable of detecting nitrosamine contaminations." Plaintiffs believe this definition is circular, and would exclude almost all documentation, as by Defendants' own telling, the only test capable of detecting nitrosamines was developed *after* the recall.

60. **Produce all documentation, including source files, for any MAUDE or other adverse event reports submitted to any regulatory agency with regard to cancer, or any injury potentially caused by valsartan contamination, and any related communications.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

61. **Produce complete files for all formal or informal adverse event reports and/or MedWatch reports concerning cancer, or any injury potentially caused by valsartan contamination, including: a) causation analyses, b) summaries (including, but not limited to, computerized data), analysis or interpretations of any such adverse event report(s) (including any post-marketing submissions); and c) documents which discuss or refer to any adverse event report, or any summary, analysis or interpretation thereof.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

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62. **Produce all databases maintained by you concerning both domestic and international formal and informal adverse event reports and/or MedWatch reports, including the underlying medical information and raw data maintained by you, with regard to reports of cancer, or any injury potentially caused by contaminated valsartan.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

63. **Produce all filings with the Securities and Exchange Commission (SEC), addressing the sale of contaminated valsartan, including Forms 10-K, 10-Q, 8-K, and proxy statement (Schedule 14A), whether such filings are tentative, final, definitive, or supplemental.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

64. **Produce complete documentation of any communications with any state regulatory or health authorities regarding valsartan purity, bioequivalence, contamination, or pricing.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

65. **Produce complete documentation of Defendant's efforts to comply with Current Good Manufacturing Practices (cGMPs), and any actions or inactions that did not meet or might not have met cGMPs, with regard to the valsartan manufacturing process and use or reuse of solvents in the valsartan manufacturing process, including, but not limited to, documents identifying any cGMP consultants retained by Defendant, documents regarding cGMP compliance provided to the FDA, and responses to FDA 483s and Warning Letters regarding cGMP compliance.**

Plaintiffs' Basis for this Request: The Parties do not dispute this request.

XIII. COMPLAINTS AND RECALLS

66. **Produce complete documentation with regard to any consideration or implementation of a recall due to contamination of valsartan.**

Plaintiffs' Basis for this Request: This request will shed light on Defendants' state of mind during the time in which they had knowledge of the contamination. This goes to the heart of Plaintiffs' negligence claims but will also show what the Defendants knew about the contamination, when, and the manner in which they decided to convey this information to customers in their supply chains, regulatory agencies, and consumers.

67. **Produce all draft recall notices with regard to contamination of valsartan.**

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Plaintiffs' Basis for this Request: Draft recall notices, compared with the final versions, are relevant to Defendants' state of mind, as well as their motive. This will be particularly true when these notices contain tracked changes or suggestions from regulators.

68. **Produce all final recall notices with regard to contamination of valsartan.**

Plaintiffs' Basis for this Request: This request will shed light on Defendants' state of mind during the time in which they had knowledge of the contamination. This goes to the heart of Plaintiffs' negligence claims but will also show what the Defendants knew about the contamination, when, and the manner in which they decided to convey this information to customers in their supply chains, regulatory agencies, and consumers. Being able to compare these final notices to the drafts requested in the request above this will allow Plaintiffs to understand what was known, compared to what was actually communicated.

69. **Produce all documents setting forth or addressing any communications with any customer or consumer relating to the recall (or non-recall) of valsartan due to contamination.**

Plaintiffs' Basis for this Request: Statements made to customers bear directly on Plaintiffs' warranty claims.

70. **Produce all communications directly with physicians relating to the recall (or non-recall) of valsartan due to contamination.**

Plaintiffs' Basis for this Request: Statements made to customers and physicians bear directly on Plaintiffs' warranty claims. They also bear on Defendants' motives in sharing information with the public about the scope and severity of the contamination.

71. **Produce all communications with any person or entity to which, or from which, you purchased or sold valsartan, with regard to valsartan contamination.**

Plaintiffs' Basis for this Request: Statements made to customers bear directly on Plaintiffs' warranty claims. They also bear on Defendants' motives in sharing information with the public about the scope and severity of the contamination.

72. **Produce all documents and communications with regard to the scope of any recall considered or implemented with regard to valsartan contamination.**

Plaintiffs' Basis for this Request: Documents relating to the scope of the recall are relevant to Defendants' state of mind and motive in executing the recall. Presumably, they are in possession of correspondence and documents which shed light on how they reached the decision to recall or not recall all valsartan they manufactured, and these impressions will be germane to Plaintiffs' negligence, failure-to-warn, misrepresentation, and fraud claims.

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73. **Produce all documents and communications with regard to any complaint or concern raised by any person or entity relating to the purity, bioequivalence, or contamination of valsartan.**

Plaintiffs' Basis for this Request: Complaints raised by others are relevant to when Defendants were placed on notice of any contamination issues.

74. **Produce all documents or communications concerning any actual or potential import or export alerts relating to valsartan contamination.**

Plaintiffs' Basis for this Request: Information about import or expert alerts is relevant to notice, as well as Defendant's motives and decision making before, during and after these alerts were imposed.

75. **Produce all documents and communications concerning any buybacks or refunds that you paid to any purchasers of valsartan in the United States related to valsartan contamination.**

Plaintiffs' Basis for this Request: Documents responsive to this request will assist in the calculation of damages for the class cases.

76. **Produce all communications (and drafts) to or from Defendant regarding recall of valsartan related to valsartan contamination, including lists sufficient to show all persons or entities who received communications.**

Plaintiffs' Basis for this Request: Documents responsive to these requests are relevant to show the scope and extent of Defendants' knowledge concerning the contamination, purity, and bioequivalence of their VCDs.

77. **Produce documents sufficient to identify any person or entity retained by Defendant with regard to the recall of valsartan due to nitrosamine contamination.**

Plaintiffs' Basis for this Request: Documents responsive to this request will allow Plaintiffs to understand what third parties may have relevant knowledge about issues germane to this MDL.

78. **Note: this request is only directed to API manufacturer defendants and FDA liaison defendants. Produce all documents setting forth or with regard to, communications with, Novartis concerning valsartan impurity, bioequivalence, or contamination.**

Plaintiffs' Basis for this Request: As Novartis was able to identify contamination in VCDs, any communications with the company relating to impurities, bioequivalence, or contamination are germane to notice.

XIV. WARRANTIES AND STATEMENTS

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79. Produce all versions of defendant's labeling, package inserts, patient leaflets, and medication guides for valsartan in the United States, together with a chart of the approval dates and in use dates for all versions that were utilized in the sale and marketing of valsartan.

Plaintiffs' Basis for this Request: These documents are relevant to Plaintiff's warranty claims, as the statements made in the labeling are given directly to physicians and patients, who relied upon them in deciding to prescribe and take VCDs.

80. Produce all statements regarding purity, bioequivalence, and contamination provided to medical professionals, purchasers including TPPs, consumers, wholesale distributors, retail pharmacies, and other direct and indirect purchasers of valsartan, for each NDC, Batch Number, and Lot Number of valsartan sold in the United States during the relevant time period.

Plaintiffs' Basis for this Request: Documents responsive to this request will shed light on Plaintiffs' warranty claims and will further allow Plaintiffs to understand the supply chain for individual valsartan lots, batches, and pills.

81. All advertisements, and sales and marketing materials for valsartan, and charts setting forth the approval date and in use dates, for each.

Plaintiffs' Basis for this Request: Documents responsive to this request will shed light on Plaintiffs' warranty claims and will further allow Plaintiffs to understand the supply chain for individual valsartan lots, batches, and pills.

82. [WITHDRAWN]

83. Produce all communications between you and any medical professional or medical association concerning the risk of cancer, or any injury potentially associated with valsartan contamination.

Plaintiffs' Basis for this Request: Communications with medical professionals and societies bear on Plaintiffs' failure-to-warn and warranty claims, as these statements have a direct impact on physicians' decisions to prescribe Defendants' drugs.

84. [WITHDRAWN]

85. Produce all communications to or from financial analysts or investors concerning the financial impact of the valsartan contamination, including but not limited to any transcripts, presentations or documents concerning any analyst conference call, or business briefing.

Plaintiffs' Basis for this Request: Documents responsive to this request will shed light on Defendants' state of mind, motive, and knowledge about the scope and extent of the contamination.

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86. Produce all communications with healthcare providers regarding the purity, bioequivalence, or, recall status, of valsartan.

Plaintiffs' Basis for this Request: Documents responsive to this request will shed light on Defendants' state of mind, motive, and knowledge about the scope and extent of the contamination. These documents will also be germane to Plaintiffs' warranty and failure to warn claims.

87. Produce all public statements (and drafts) issued by Defendant regarding valsartan purity, bioequivalence, or contamination of valsartan.

Plaintiffs' Basis for this Request: Documents responsive to this request will shed light on Defendants' state of mind, motive, and knowledge about the scope and extent of the contamination. These documents will also be germane to Plaintiffs' warranty, failure to warn claims, as well as claims sounding in misrepresentation and fraud.

88. [WITHDRAWN]

89. [WITHDRAWN]

90. Produce all communications with the Centers for Disease Control (CDC), National Institutes of Health, World Health Organization, U.S. Drug Enforcement Agency, U.S. Department of Justice, U.S. Attorney General, any regulatory agency, or any state agency, relating to valsartan contamination.

Plaintiffs' Basis for this Request: Documents provided to government organizations are relevant to notice, Defendants' knowledge about the scope and extent of the contamination issue. Moreover, the information being communicated to the American public and its representatives is relevant to Defendants' state of mind.

91. Produce all documents relating to any investigative subpoenas and subsequent investigation from the United States Department of Justice, United States Congress, and/or any other federal or state entity, relating to valsartan contamination.

Plaintiffs' Basis for this Request: Documents provided to government organizations are relevant to notice, Defendants' knowledge about the scope and extent of the contamination issue. Moreover, the information being communicated to the American public and its representatives is relevant to Defendants' state of mind.

92. Produce all documents relating to, referring to or embodying any discussion or submission between defendant and any state government regulatory agency or any state medical society concerning reimbursement for valsartan purchases.

Plaintiffs' Basis for this Request: Statements concerning reimbursement are relevant to proving damages in the class cases and will be necessary for Plaintiffs' experts to consider in their damages model.

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XV. SALE AND DISTRIBUTION

93. Produce complete documentation setting forth and/or demonstrating the complete supply and distribution chain for valsartan purchased, sold, or distributed by you, from the manufacture of the API through the final sale to the consumer.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

94. Produce all documents relating to the sale and distribution of valsartan that reflect NDC, batch number, and lot number.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

95. Produce documents sufficient to show all sales of valsartan to wholesalers, distributers, retailers, and consumers, including the total net sales, total number of pills and/or units sold, unit price, unit cost, profit margin, and market share by state or territory.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

96. Produce all documentation relating to the due diligence performed (or meant to be performed) in selecting an API or finished dose manufacturer from which you purchased valsartan, including but not limited to policies and standard operating procedures.

Plaintiffs' Basis for this Request: Plaintiffs require these documents because they are relevant to the Finished Dose Manufacturers' compliance with cGMPs.

97. Produce all communications received from any API manufacturer or finished dose manufacturer with regard to the manufacturing process, purity, bioequivalence or contamination relating to valsartan.

Plaintiffs' Basis for this Request: Plaintiffs require these documents because they are relevant to the Finished Dose Manufacturers' compliance with cGMPs.

98. Produce complete documentation of the basis for Defendant's decision to purchase valsartan from any API or finished dose manufacturer, including documents you reviewed or relied on to make those decisions.

Plaintiffs' Basis for this Request: Plaintiffs require these documents because they are relevant to the Finished Dose Manufacturers' compliance with cGMPs.

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XVI. IDENTIFICATION OF PURCHASERS

99. Produce documents sufficient to identify all persons and entities (including consumers and TPP entities) who purchased, reimbursed, or paid or otherwise compensated you for valsartan you manufactured, sold or distributed in the United States. If available, produce documents sufficient to show these individuals' or entities' names, last known mailing addresses and email addresses, last known telephone numbers, date(s) of purchase, NDC Code(s), Batch Number(s), and Lot Numbers.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

100. Produce all communications between or among you and any named plaintiff, including consumers and/or TPP entities, including but not limited to MSP Recovery Services (including its assignors, Summacare, Emblem, and Connecticare) and Maine Automobile Dealers Association, with regard to the sale of valsartan.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

XVII. SALES AND PRICING

101. Produce complete documentation demonstrating all valsartan sales you made in the United States to any purchaser (including, but not limited to, wholesalers, distributors, retailers and retail consumers), including documents that reflect total gross sales, total net sales, total number of units sold, unit price (gross and net), unit cost, cost of goods sold, profit margin, NDC, batch number, and lot number, on an annual basis, by, defendant, state, territory or the District of Columbia.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

102. Produce all documents and communications indicating your market share for valsartan, or competition for market share for valsartan, in the United States including, but not limited to, regularly updated forecasts, life cycle forecasts, internal tracking documents, product launch plans, market share audits, and documents analyzing IQVIA or IMS data.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

103. All documents and communications relating to negotiations over price and terms of sale or distribution between any defendant and any purchaser or re-seller of valsartan including, but not limited to, requests for proposals ("RFPs) for chain pharmacies and/or wholesalers, full line bids, product offers related to VCDs, presentations regarding bids or proposals, and portfolio management programs.

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Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

104. Produce all documents and communications relating to any agreements or arrangements between you and any TPP entity (or any person acting on behalf of a TPP entity) that did, could, or may affect the quantity or price of valsartan purchased (including e.g., rebate agreements provided to pharmacy benefit managers ("PBMs"), purchasing agreements with PBMs, shelf stock adjustments and/or credits provided to PBMs, etc.).

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

105. Produce complete documentation of any arrangements between you and any other wholesaler or chain pharmacy that did, could, or may affect the quantity or price of valsartan purchased, including but not limited to rebate agreements, volume incentives, pride reduction offers, profit splits arrangements, shelf stock adjustments, new product launch generic conversation programs, and all reimbursements and/or penalties paid as a result of recalls.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

106. Documents identifying all retailers and/or sellers (including but not limited to, retail pharmacies, mail order pharmacies) who have offered valsartan for sale in the United States and territories from January 1, 2010 to the present, including but not limited to the name, location, and sales volume for each such retailer, as well as the relevant NDC, Batch Numbers, and Lot Numbers for each seller or retailer, where available.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

107. Produce complete documentation of your actual and projected valsartan sales, including:

a. **List price;**
b. **Average marginal price;**
c. **Average wholesale price;**
d. **Wholesale acquisition cost;**
e. **Direct price;**
f. **Average discount off of wholesale price or wholesale acquisition cost;**
g. **Price under Medicare program;**
h. **Price under Medicaid program;**
i. **Maximum allowable price;**

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j. **Average manufacturing price (AMP) as defined by, and reported to, the Centers for Medicare and Medicaid Services;**
k. **Best price, as defined by, and reported to, the Centers for Medicare and Medicaid Services;**
l. **Net revenue;**
m. **Gross sales;**
n. **Net sales;**
o. **Units;**
p. **Gross shipments;**
q. **All measures of margin, income, earnings, and profits;**
r. **Unit of volumes sold;**
s. **Unit of volumes sold net of returns;**
t. **Total product contribution;**
u. **All costs and expenses attributable to the product;**
v. **Sales and distribution cost;**
w. **Cost of goods sold;**
x. **Manufacturing costs;**
y. **Marketing, advertising, promotional, and sales expenses;**
z. **Depreciable and capital improvements;**
aa. **Regulatory compliance;**
bb. **Short-run average variable costs;**
cc. **Long-run average variable costs;**
dd. **Fixed costs;**
ee. **Materials cost;**
ff. **Labor cost;**
gg. **Marginal cost;**
hh. **Rebates, discounts, vouchers, or other product promotions, returns, or charge-backs; and**
ii. **Coupons or co-pay cards.**

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

108. Documents identifying every entity that purchased, reimbursed, or compensated you for valsartan.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

109. Produce all contracts for the sale of valsartan, including (a) contracts with direct purchasers; (b) contracts that provide that the purchaser will take delivery of valsartan from another entity (such as a wholesaler); and (c) contracts concerning or regarding the payment of chargebacks.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

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110. Produce complete documentation of the date, manufacturing source, quantity, and recipient of all samples of valsartan provided by Defendant.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

111. Produce all electronic data in tab-delimited, comma-delimited, or semicolon-delimited ASCII flat text or similar electronic format from January 1, 2010 to the present sufficient to identify all sales of valsartan to purchasers in transaction-by-transaction format, as follows:

a. **All direct sales/invoice transactions (as well as any discounts or any other price adjustments or offsets contained in the transaction data) including the following fields: (i) price or dollar amount, (ii) source of the transaction price, (iii) number of units sold, (iv) number of units returned or otherwise affected by the transaction, (v) unit of measure, (vi) date of transaction, (vii) information sufficient to identify the type of transaction (e.g., a sale, a return, a discount, etc.), (viii) NDC, (ix) UPC, (x) SKU, (xi) product description, (xii) product form, (xiii) strength, (xiv) package size in extended units per package, (xv) customer name, (xvi) customer number, (xvii) customer address, (xviii) customer class of trade code and the description of that code (all such customer information being provided for both the bill-to and ship-to customer), and (xix) the customer's parent company (if the data identifies a subsidiary, corporate affiliate, division, satellite office, distribution center, warehouse, or the like).**

b. **All data concerning chargebacks, rebates, discounts, and other consideration given or accrued relating to valsartan, including the following fields: (i) each transaction, including the date thereof; (ii) the name and address of, and all unique codes or identifiers for, the person, firm corporation, or other business entity whom you paid, or on whose behalf you accrued, the chargeback, rebate, discount and/or other consideration; (iii) the name and address of, and all unique codes or identifiers for, the persons, firms, corporations, or other business entities that made the purchases in respect of which you paid or accrued the chargeback, rebate, discount, or other consideration; (iv) the sales, or groups of sales, upon which the rebate, discount, or other consideration is based, including: (aa) the number of units of the particular product sold, by package size, SKU, UPC, NDC, and any and all other unique codes or other identifiers for each sale or other transaction; (bb) the bill-to customer; (cc) the ship-to customer; (dd) the dates of the sales, or group of sales; (ee) the invoice amount in dollars for the sales or group of sales; (ff) the amount of the chargeback, rebate, discount, or other consideration paid or accrued; and (gg) the contract, agreement, or other basis upon which the chargeback, rebate, discount, or other consideration is calculated.**

c. **All administrative fee transactions relating to valsartan, including: (i) fee amount paid, (ii) date of payment, (iii) date or date range of sales concerning the fee that was paid, (iv) information sufficient to identify the type of**

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administrative fee (if applicable), (v) customer name, (vi) customer number, (vii) customer address, and (viii) customer class of trade code and the description of that code;

d. **For all other transaction types not reflected in (a) through (c) above, produce all documents relating to any other paid or accrued discounts, rebates, chargebacks, billbacks, unit adjustments, price adjustments, shelf-stock price adjustments, returns, third-party returns, error corrections, free goods, nominally-priced goods, whether created or maintained daily, monthly, quarterly, or at some other periodicity, with regard to valsartan.**

e. **The complete documentation for all items above (a though d) including (i) lookup tables, (ii) data dictionaries, (iii) lists of fields, (iv) descriptions of information contained in those fields (e.g., field lengths, formats, etc.), and (v) descriptions of any codes used in any fields (such as class of trade designations, etc.), including but not limited to (aa) a separate product list, including NDC, SKU, UPC, product description, and package size; (bb) a separate table that lists, for each "bill-to customer" and "ship-to customer," the customer number, parent customer number, customer group number, customer identity, contact information, address, and class of trade (e.g., SIC code); (cc) a separate table listing and defining each transaction code, abbreviation, or other field or entry code, and indicating (1) whether quantity values for each transaction type should be included in calculating net quantity sold, or should be ignored because they do not affect net quantity sold and (2) how negative unit and dollar values should be treated in calculating net quantities and dollar amounts; (dd) all data sets and calculations used to (1) determine accrued rebates and/or chargebacks and/or (2) periodically reconcile accrued rebates and/or chargebacks with actual rebates and/or chargebacks; (vi) return and/or exchange policies; and (vii) payment terms.**

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

XVIII. AVAILABLE DATA SOURCES

112. Produce all documents relating to all IMS, Verispan, MediSpan, Scott-Levin, PriceCheck, ImpactRx, First DataBank, or other pharmaceutical industry data products purchased and or subscribed to or available to you regarding valsartan.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

113. Produce all data or reports generated by IMS, CMS, or Verispan, or any comparable third party person or entity (including, but not limited to, Medi-Span, ImpactRx, and First DataBank), in whatever format it was received, relating to the sale, prescription, marketing, promotion, or detailing of valsartan from date of launch to the present for valsartan, including:

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a. **IMS National Prescription Audit data, including TRx, NRx, extended units, retail sales dollars and retail sales price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.**
b. **IMS National Sales Perspective data, including total units, extended units, total sales dollars, and price. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.**
c. **CMS national Health Expenditures and Drug Utilization data, including TRx, NRx, Medicaid percentage paid, extended units, retail sales dollars, and retail sales price, with regard to valsartan.**
d. **Verispan Vector One National (VONA) data, including TRx, NRx, extended units, retail sales dollars, and retail sales price, with regard to valsartan. Preferably, the data should be broken out by manufacturer, product, form, strength, NDC, and channel.**

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

114. Produce all documents relating to any coupon or co-pay assistance you made available to consumers for valsartan.

Plaintiffs' Basis for this Request: Plaintiffs require this information to calculate their damages for their economic loss claims and for class certification.

XIX. DEFENDANT-SPECIFIC REQUESTS

A. To Mylan:

115. Produce all documents, communications, and filings associated with Mylan's ANDA 204743. This includes but is not limited to the initial ANDA submission, subsequent amendments to the ANDA submission, correspondence from the FDA regarding that ANDA submission, responses to correspondence from the FDA regarding that ANDA submission, and any and all supporting documentation filed with the FDA, including bioequivalence information, manufacturing information, and testing regarding ANDA 204743.

Plaintiffs' Basis for this Request: To the extent the Court orders discovery of unapproved, tentatively approved or withdrawn ANDAs, this request would subsume the Court's ruling.

116. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan's Nashik facility, including but not limited to the September 2016 inspection and resulting warning letter and November 2018 inspection and warning letter.

Plaintiffs' Basis for this Request: Mylan has agreed to produce this (and all other inspection documents related to their three finished dose manufacturing facilities.

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117. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Mylan's Morgantown, WV facility, including but not limited to documents regarding inspections which occurred in November of 2016, March 2018, April 2018, resulting correspondence with the FDA regarding these inspections (including but not limited to, notes, presentations and documents created as a result of in person meetings with regulatory officials).

Plaintiffs' Basis for this Request: Mylan has agreed to produce this (and all other inspection documents related to their three finished dose manufacturing facilities.

118. Produce due diligence documents addressing valsartan bioequivalence, purity, and contamination, associated with Mylan's acquisition of Matrix Pharmaceuticals.

Plaintiffs' Basis for this Request: Plaintiffs have agreed to withdraw this request.

119. Produce all documents and communications regarding your contract with Lantech Pharmaceuticals for the recovery and further use of any and all solvents used in valsartan manufacturing.

Plaintiffs' Basis for this Request: There is no dispute with this request.

B. To Aurobindo:

120. All documents and communications regarding your contract with Lantech Pharmaceuticals for the recovery and further use of any and all solvents used in valsartan manufacturing.

Plaintiffs' Basis for this Request: Lantech Pharmaceuticals, and their flawed solvent recovery process, is directly responsible for the contamination of Aurobindo's API

C. To Teva:

121. Produce all full and complete documents and document families previously produced in core discovery, including all documents previously withheld by Teva from the custodial file of Constance Truemper.

Plaintiffs' Basis for this Request: There is no dispute with this request.

122. Produce all inspection documents, including any and all Form 483s, and EIRs, and correspondence from the FDA associated with Teva's finished dose manufacturing facilities, including but not limited to the Jerusalem Oral Solid Dose facility, and documents regarding a 2010 inspection which resulted in a warning letter from the FDA.

Plaintiffs' Basis for this Request: There is no dispute with this request.